Japan

Type of Market: Large/Challenging

Japan ranked as the top country in this *Health IT Top Markets Report,* with a favorable demographic profile for Health IT, a largely urbanized population, and sizable current market, coupled with significant ICT and healthcare investments in place. The U.S. and Japan have already engaged in several Health IT information exchanges to date, forming a good foundation for future collaboration. However, several challenges currently exist for Health IT companies doing business in Japan, including a lack of specific Health IT policies, and numerous government agencies playing a role in sector oversight, leading to areas of policy fragmentation.

Overall Rank

1

Japan held the top position among the 80 countries ranked, and rates highly on many Report metrics. For instance, Japan has the third highest GDP level globally (behind only the United States and China); a large Health IT market size (exceeding $1 billion); the oldest-skewing population distribution; a high concentration of population clustered in urban areas; a tech-friendly society; and very good Health IT infrastructure. All of these factors indicate that Health IT already has a good foundation in Japan, with the potential for more growth. However, some important caution areas exist regarding access to Japan's Health IT market, particularly in areas not directly measured by this Report's methodology.

Challenges in the Market

The regulatory environment represents one important challenge to consider when evaluating Health IT market opportunities in Japan. At present, multiple ministries play distinct roles in Health IT oversight:

- Ministry of Economy, Trade and Industry (METI) has the lead in Health IT services and commercial engagement;
- Ministry of Health, Labour and Welfare (MHLW) leads on pharmaceuticals, medical devices, promotion of health products, and home healthcare;
- Ministry of Information and Communication (MIC) leads on telecom policy, privacy and open data;
- Consumer Affairs Agency leads on protection of personal information, with the above

agencies and the Ministry of Internal Affairs and Communications providing guidance on regulations; and

- Ministry of Education, Culture, Sports, Science and Technology (MEXT) oversees university hospitals.

One example of the overlapping responsibilities concerns privacy and protection of personal information, as provisions vary among government agencies, and local governments may also impose rules. Consequently, this creates challenges for Health IT companies (particularly those in cloud computing and data analytics) to conform to the inconsistent rules of government bodies.

Since no agency has the clear lead role in overseeing all aspects of Health IT, and significant areas of the sector are not currently governed by rules and regulations, the result is regulatory and policy fragmentation, creating uncertainty regarding the rules U.S.-based companies will confront when entering the market. In 2014, the Government of Japan announced that a review of the Personal Information Protection Law would take place in an effort to facilitate data collection and analysis while ensuring personal information protection. As of late April 2015, a bill amending the Protection Law had been submitted and was under Diet deliberation. Regulations currently are also in effect regarding mobile technologies and population health.

Figure 1: Aging and Contracting Population
Japan's Demographics
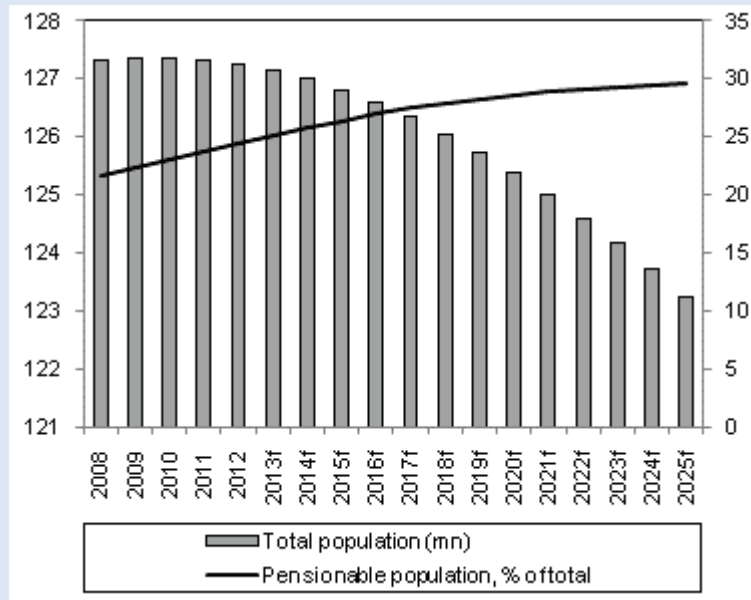
Source: Business Monitor International

A second issue is a recent policy decision that the Social Security and Tax Number System, My Number System, (to be implemented in 2016) will not contain medical information. A separate system will be developed to handle the medical data, which has the potential to create system integration challenges for commercial and public health efforts that desire to effectively share patient information so that treatment decisions can be based on a complete patient record. MHLW would like to link these systems, but privacy concerns among Japanese citizens will not allow this to happen. In addition, the Japanese government has recently decided to postpone a planned consumption tax increase, where the additional revenue would have targeted social security and welfare, with health as a significant beneficiary. The Diet is deliberating amendment of legislation related to these topics together with the review of the Protection Law.

Another factor that could inhibit increased uptake of Health IT in Japan is the absence of Chief Information Officers (CIOs), Chief Medical Officers (CMOs) and Chief Medical Information Officers (CMIOs) at most hospitals. In the United States, CIOs, CMOs and CMIOs are often integral players in decision-making regarding the purchase of, and need for, health information systems, and often serve as advocates for purchasing integrated systems. In Japan, there is often no hospital official available (or sufficiently informed) to advocate

for the installation of Health IT systems. In addition, most systems are developed for use by individual hospitals, and are not designed for information sharing between facilities.

Hospitals usually purchase Health IT in two different ways: public hospitals publish their own procurements for Health IT products and services, particularly information management systems, and have a lot of autonomy. In contrast, purchasing by national university hospitals falls under MEXT's purview. The procurement processes used within both sets of hospitals often lack transparency.

There are several local companies active in the sector. These include Hitachi, who is focusing on "social innovation business" and development of healthcare infrastructure; a wristwatch sensor terminal; and "brain science," with a focus on healthcare and medical care. Others include Toshiba, Sony, Fujitsu, and Ricoh.

A fairly strong infrastructure exists for delivering Health IT in Japan, with 3G and 4G systems and high-speed broadband Internet widely available. Japan is a highly urbanized country, and the prevalence of Internet connectivity (82.8 percent, from MIC) may result in less mobile health and telehealth deployment in Japan than otherwise indicated by this Report's top

Figure 2: High Government Expenditure
Japan's Health Expenditure by Sector (JP Yen, billion)
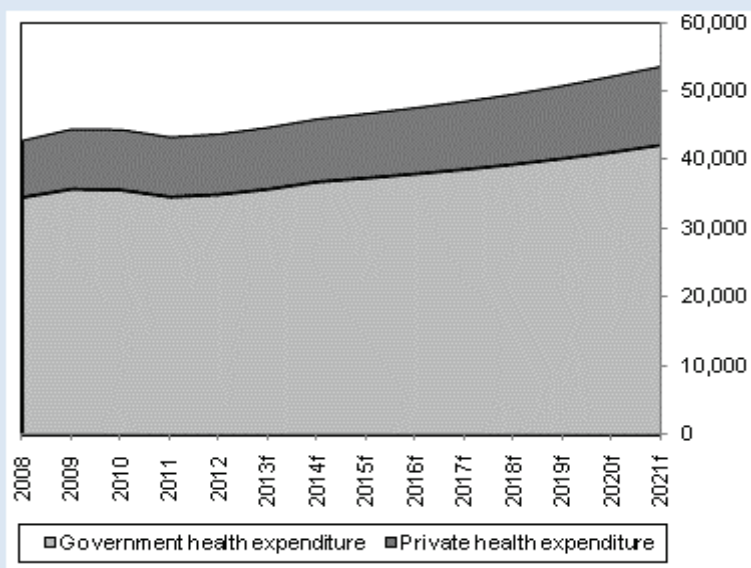
Source: Business Monitor International and World Health Organization

ranking. However, an offsetting point would be that the more consistent collection and measurement of vital health information, and associated need to control health costs, might drive the Japanese to implement more mobile and telehealth services for those reasons.

Finally, Article 20 of Japan's Medical Law is ambiguous regarding the status of telemedicine, and may contain language that prohibits telemedicine. As a result, with no explicit guidelines or rules, the Medical Law is unclear about which medical specialists can practice telemedicine. However, a March 31, 2011 MHLW ordinance (in the aftermath of the eastern Japan earthquake and tsunami) "accepted telemedicine under the same conditions as face-to-face treatment."[56] Revision of Article 20 was a February 2014 recommendation from the American Chamber of Commerce-Japan (ACCJ) to promote the growth of telemedicine in Japan (more information below).

Opportunities for U.S. companies

The government's plans to revamp healthcare services are unsurprising given Japan's demographics (see Figure 1). In 2012, people over age 65 represented 24.4 percent of Japan's population. This proportion is projected to reach 29.6 percent by 2025 and 36.5 percent by 2050, and will be particularly impactful given the shrinking overall population in the next

decade. With the ageing population, the burden of non-communicable diseases is much higher than communicable diseases. These often-chronic diseases - cardiovascular and metabolic disorders, cancer, diabetes, Alzheimer's disease and other mental health problems – normally require prolonged treatment. An increased focus on home care (including mobile health and telehealth) will decrease the country's reliance on hospitals, allowing patients to receive proper care from home and leaving sufficient beds in hospitals for more urgent cases.

Despite the government's best attempts, the financial burden of providing generous healthcare benefits for the population is proving unsustainable, especially in slow-growth, developed markets like Japan.[57] In 2012, government healthcare expenditure reached Japanese (JP) Yen 35,093 billion (US $439.5 billion) accounting for 80 percent of total expenditure on healthcare (see Figure 2).

As a result, private sector healthcare provision in Japan (through improved home care and community-based care, aided by mobile health and telehealth) will likely become a greater proportion of treatment services, particularly for the elderly population.

A variety of U.S. Health IT companies have expressed interest in the Japanese market in recent years. Companies with a wide range of products/services to

offer (including nurse call systems, administrative claims, and data exchange technologies) have approached the International Trade Administration for assistance, and large, multinational companies (such as Intel, Apple, and IBM) also have a presence in the market.

ACCJ is a key stakeholder driving interest in Health IT between the U.S. and Japanese governments. In February 2014, the ACCJ issued the report "Utilizing Telemedicine to Deliver More Efficient and Effective Healthcare in Japan," which contained the following recommendations:

1) Revise Article 20 of the Medical Law (referenced above), particularly clarifying who can practice telemedicine, and broaden the scope of practitioners beyond medical doctors;
2) Clearly define reimbursement qualifications and expand the number of telemedicine services eligible for reimbursement;
3) Speed up the implementation of the "*Dokodemo MY Byouin* (My Hospital Everywhere) Project and complete and implement the "National ID" or "Common ID" number system (the Social Security and Tax System referenced above) as soon as possible;
4) Continue efforts and create incentives to increase EHR use to 50 percent or more within three years, and encourage greater data interoperability between medical facilities;
5) Harmonize privacy and personal information rules among competent government bodies for use of Big Data and analytics in cloud computing environments;
6) Introduce a policy framework that promotes delivery of telehealth services and supports companies willing to invest and develop new business models in this emerging sector;
7) Improve coordination across the various ministries involved in regulating the sector; and
8) Implement existing global telehealth standards and assume a leadership role in the ongoing development of future global standards.

In 2013, the American Health Information Management Association (AHIMA), through a project supported by the ITA, launched an effort to develop a global health information management curriculum to instruct new entrants to Health IT (students and those switching careers), as well as career healthcare workers, on appropriate governance and data analysis techniques. This initiative involves experts from countries worldwide, including Yukiko Yokobori of the Japan Hospital Association.

The curriculum is currently under review by education and workforce experts, and may be ready for implementation worldwide by mid-2015. Japan would significantly benefit by being an early adopter of the finalized curriculum and introducing the coursework into universities and professional development institutions to address their Health IT workforce shortage and possibly increase adoption of Health IT technologies.

Japanese and U.S. Government and private sector representatives have also engaged in a series of meetings in recent years, forming a good foundation for future discussions. These include the following:

1) A 2013 week-long interagency delegation visit to Japan by representatives from HHS (Office of National Coordinator), Veterans Administration, ITA, and National Institute of Standards and Technology. The visit included meetings with Japanese ministries (MHLW, METI, MIC, MOFA), as well as industry, legislative, academic and trade association officials (more details on this trip below);
2) The 2013 and 2014 meetings of the U.S.-Japan Internet Economy Dialogue, which singled out healthcare as one of the major areas of potential cooperation;
3) A September 2014 meeting in Washington including U.S. Government, Keidanren, ACCJ and industry trade associations;
4) U.S. Government meetings with representatives of the Japanese Association of Healthcare Information Systems Industry (JAHIS) at HIMSS Annual Conference, 2013-14; and
5) Meetings with Japanese Embassy in 2013-14.

ACCJ and industry identified five possible Health IT areas of cooperation through the U.S.-Japan Internet Economy Dialogue: 1) healthcare data standardization, 2) healthcare big data and data utilization, 3) privacy and security, 4) How IT plays a role in National Health Insurance, and 5) preventative care and IT.

Some follow-up opportunities identified during the September 2013 U.S. delegation visit include:

1) Addressing the shortage of Health IT workers in Japan;
2) Advising Japan on efforts to standardize data exchange (such as the "SS-Mix" system);
3) Meeting with city and local government officials leading the effort on piloting new Health IT products and services (may include Shimane, Kanagawa, and Okayama prefectures);
4) Focusing on disease prevention, rather than treatment of chronic disease;
5) Pursuing METI interest in supporting private sector initiatives;
6) Educating Japanese officials on lessons learned from U.S. Health IT rollout;
7) Encouraging increased Japanese involvement and activity with international Health IT standards-setting bodies; and
8) Discuss transition of Health IT pilot projects in Japan to long-term sustainability.

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